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**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO**

CALVIN TIMBERLAKE AND	§	CASE NO. CV 08 80067MISC VRW
KAREN TIMBERLAKE,	§	
Plaintiffs,	§	S.D. Texas Civil Action No.
	§	
VS.	§	6:08-CV-00004
	§	Hearing Stayed by Order
	§	Dated April 25, 2008
SYNTHEX SPINE COMPANY, L.P., et. al.,	§	
Defendants.	§	

**PLAINTIFFS' RESPONSE AND BRIEF IN OPPOSITION TO DEFENDANT SYNTHES
SPINE COMPANY, L.P.'S MOTION TO QUASH OR, IN THE ALTERNATIVE, STAY
PLAINTIFFS' THIRD-PARTY SUBPOENA ON JIM ZUCHERMAN, M.D.**

COMES NOW, Plaintiffs, Calvin Timberlake and Karen Timberlake, and files their Response and Brief in Opposition to Defendant Synthes Spine Company, L.P.'S Motion To Quash Or, In The Alternative, Stay Plaintiffs' Third-Party Subpoena On Jim Zucherman, M.D. and asks the court to deny same.

STATEMENT OF ISSUES TO BE DECIDED

This action seeks damages for devastating injuries sustained by Plaintiff Calvin Timberlake from the failure of a ProDisc, an artificial disc marketed by Defendant Synthes Spine Company, L.P. ("Synthes"), inserted in his lumbar spine in order to replace a degenerated disc. Plaintiffs' complaint alleges, in part, that many of the physicians performing clinical trials on the ProDisc, which led to its approval by the Food and Drug Administration (FDA), were investors in the venture who, to protect their financial stake in the outcome of the trials, deliberately omitted unfavorable outcomes from the reported results.¹ In order to gather evidence germane to this allegation, Plaintiffs issued subpoenas to these physicians, seeking information concerning their financial interest in the ProDisc, their communications to the FDA regarding it, and their clinical trials evaluating it.²

Pending before the Court is Synthes Spine Company, L.P.'S Motion To Quash Or, In The Alternative, Stay Plaintiffs' Third-Party Subpoena On Jim Zucherman, M.D. precluding the discovery sought by these subpoenas. The motion advances four objections: (1) they are overly broad and unduly burdensome, since they are unrestricted as to scope and time, and are not limited

¹Plaintiffs' First Amended Original Complaint ¶¶ 14, 16.

² Plaintiffs' Third Party Subpoena (Synthes Ex B).

to the treatment of Plaintiff Calvin Timberlake; (2) they are not reasonably calculated to lead to the discovery of admissible evidence, again because they are not limited to Mr. Timberlake, and further because Plaintiffs' claims are preempted, thus making the information irrelevant to any viable cause of action; (3) they seek Synthes' proprietary trade secrets; and (4) they seek confidential patient information.³

Some of the foregoing objections (nos. 3 and 4) have merit, but do not support the denial of discovery requested by Synthes' motion. The other objections (nos. 1 and 2) are devoid of merit. Specifically:

1. The subpoenas are not limited to the treatment of Mr. Timberlake for a very sound reason—i.e., their whole purpose is to learn about clinical trials *before* Mr. Timberlake's operation. Furthermore, the nature of the requests places inherent restrictions upon their scope and time. They are, after all, limited to clinical trials about the ProDisc, which necessarily occurred over a discrete and relatively brief duration easily understood by Synthes and the physicians from whom the information has been requested.
2. The subpoenas are not limited to Mr. Timberlake for the reason explained above. Plaintiffs' claims, moreover, are *not* preempted.
3. The trade secret objection can be resolved by a confidentiality agreement.
4. Patient confidentiality can be preserved by redacting any information which reveals the patient's identity.

In sum, Plaintiffs are willing to agree to reasonable restrictions needed to address Synthes' legitimate concerns, such as executing a confidentiality agreement to protect Synthes' trade secrets, and redacting from clinical trial records information identifying the patient. But Plaintiffs are entitled to the discovery at issue. Hence, subject to these limits, Synthes' motion should be denied.

³ Synthes Brief in Support of Motion to Quash ¶ 5.

ARGUMENT

I. THE SUBPOENAS ARE NEITHER OVERLY BROAD NOR UNDULY BURDENSOME.

Synthes' objection that the subpoenas are unrestricted as to scope and time is untenable.⁴ Their scope, first of all, is limited to the ProDisc—even more specifically, indeed, to the physicians' financial interest in the ProDisc, their communications to the FDA regarding it, and their clinical trials evaluating it. It would be virtually impossible to narrow the requests further without gutting the substantive information required to pursue Plaintiffs' claims.

Their limited scope, moreover, also refutes the notion that the subpoenas are unrestricted as to time. In a trivial sense, Synthes is correct: the subpoenas do not explicitly recite a range of dates. But they do not need to. The very scope of the requests places inherent restrictions upon the time encompassed, which necessarily began with the physicians' involvement (financial or clinical) with the ProDisc, and ended with FDA approval. The complaint alleges that investor physicians were solicited to participate in the clinical trials required for FDA approval no earlier than May 2001,⁵ and that the FDA approved the ProDisc in August 2006.⁶ Thus the maximum span of time covered by the requests is a roughly 5-year period, a discrete and relatively brief duration easily understood both by Synthes and by the physicians from whom the information has been requested.

Equally immaterial is Synthes' objection that the subpoenas are not limited to the treatment of Plaintiff Calvin Timberlake.⁷ Of course not. Their whole purpose, after all, is to elicit

⁴ Synthes Brief in Support of Motion to Quash p. 6-7.

⁵ Plaintiffs' First Amended Original Complaint ¶¶ 30, 35.

⁶ Plaintiffs' First Amended Original Complaint ¶ 18.

⁷ Synthes Brief in Support of Motion to Quash, p. 7.

information about clinical trials *before* Mr. Timberlake's operation. The implausible logic of Synthes' objection is that patients injured by medical devices, whose unfitness is shown by antecedent studies, can never gain access to those studies needed to prove the device's unfitness. The injustice of this proposition is self-evident. Not surprisingly, it has been repeatedly rejected. *See, e.g., In re Prempro Prods. Liab. Litig.*, 2006 WL 751299 (E.D. Ark. Mar. 20, 2006) (denying motion to quash subpoena relating to clinical trials); *In re Zyprexa Prods. Liab. Litig.*, 2005 WL 2237793 (E.D.N.Y. Apr 7, 2005) (ordering production of clinical trial data); *In re Rezulin Prods. Liab. Litig.*, 178 F. Supp. 2d 412 (S.D.N.Y. 2001) (denying motion to quash subpoenas to physicians who participated in clinical trials, compelling them to produce medical records of patients who were the subjects of those trials); *Grundberg v. Upjohn Co.*, 137 F.R.D. 365, 371 (D. Utah 1991) (overruling drug manufacturer's objection to subpoena to produce data underlying clinical study reports submitted to FDA because "[t]he reports are relevant on the issue of what was submitted to the FDA").

II. THE SUBPOENAS ARE REASONABLY CALCULATED TO LEAD TO THE DISCOVERY OF ADMISSIBLE EVIDENCE.

Synthes' assertion that the subpoenas are not calculated to lead to the discovery of admissible evidence rests upon two grounds, one of which—that they are not limited to Mr. Timberlake—has already been addressed, and need not be belabored again.⁸ The other ground is that Plaintiffs' claims are supposedly preempted. This, too, is unavailing.

Preemption is, to be sure, a defense in product liability actions involving medical devices. However, Synthes greatly exaggerates the scope of preemption, and neither of the two cases it cites, *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 121 S.Ct. 1012, 148 L.Ed.2d 854 (2001),

and *Riegel v. Medtronic, Inc.*, 128 S.Ct. 999, 169 L.Ed.2d 892 (2008), supports its argument. To the contrary, these cases underscore the flaws in Synthes' categorical preemption theory.

The plaintiffs in *Buckman*, for example, alleged that the defendant made false representations to the FDA in obtaining approval of for an orthopedic bone screw. The Supreme Court held that "plaintiffs' state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, federal law." 531 U.S. at 348, 121 S.Ct. at 1017. *Buckman* means exactly what it says; i.e., fraud-on-the-FDA claims are preempted. Hence, as numerous court have held, claims alleging fraud on patients or their physicians are *not* preempted. See, e.g., *In re Medtronic, Inc., Implantable Defibrillators Litig.*, 465 F. Supp. 2d 886 (D. Minn. 2006); *Steele v. Depuy Orthopaedics, Inc.*, 295 F. Supp. 2d 439 (D.N.J. 2003); *Woods v. Gliatech, Inc.*, 218 F. Supp. 2d 802 (W.D. Va. 2002); *Bouchard v. American Home Prods. Corp.*, 213 F. Supp. 2d 802 (N.D. Ohio 2002). Such non-preempted claims are alleged in the case at bar. See Plaintiffs' First Amended Original Complaint ¶¶ 14, 47-51.

Riegel v. Medtronic, Inc., *supra*, exposes yet another gap in Synthes' monolithic preemption theory. *Riegel* holds that the preemption provision of the Medical Device Amendments of 1976, 21 U.S.C. § 360k, does *not* apply to state law claims based on a violation of FDA regulations:

State requirements are pre-empted under the MDA only to the extent that they are "different from, or in addition to" the requirements imposed by federal law. § 360k(a)(1). Thus, § 360k *does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case "parallel," rather than add to, federal requirements.*

⁸ Synthes Brief in Support of Motion to Quash, p. 7.

128 S.Ct. at 1011 (emphasis added).⁹ Again, such claims are alleged in the present case. Among Plaintiffs' grievances are the investigating physicians' financial stake in ProDisc. And, as Synthes itself acknowledges,¹⁰ FDA regulations govern the qualifications of investigators, discouraging, in particular, their having a financial interest in the outcome of the study. *See, e.g.*, 21 C.F.R. § 54.1(b) ("[o]ne potential source of bias in clinical studies is a financial interest of the clinical investigator in the outcome of the study"). A further point-by-point refutation of Synthes' preemption theory is not feasible for the simple reason that Synthes has not articulated it beyond the sweeping assertion that all of Plaintiffs' claims are preempted, and its reservation of a right to file a dispositive motion based on preemption.¹¹

III. SYNTHES' TRADE SECRETS CAN BE ADEQUATELY PROTECTED BY A CONFIDENTIALITY AGREEMENT.

While the information at issue here may well include proprietary trade secrets, as Synthes contends, a complete ban on discovery is unnecessary, for there exists a less restrictive, yet equally effective, alternative; namely, a confidentiality agreement.¹² *See* Fed. R. Civ. P. 26(c)(1)(G) (a protective order may require that trade secrets and other confidential information be disclosed only under certain conditions); *Riley v. Walgreen Co.*, 233 F.R.D. 496, 501 (S.D. Tex. 2005); *In re Zyprexa Prods. Liab. Litig.*, *supra* (ordering production of clinical trial data subject to confidentiality agreement). Plaintiffs will attempt to negotiate an agreement with Synthes; but,

⁹The Supreme Court nevertheless affirmed a dismissal of the plaintiffs' claims, on preemption grounds, but only because the plaintiffs failed to raise the issue in the court of appeals or in their petition for certiorari. *See* 128 S.Ct. at 1011 ("[w]e decline to address that argument in the first instance here").

¹⁰*See* Defendant Synthes Spine Company, L.P.'s Brief in Support of Motion to Quash, p. 11 (citing 21 C.F.R. § 812.119).

¹¹Defendant Synthes Spine Company, L.P.'s Brief in Support of Motion to Quash, p. 11, footnote 6.

¹²*See* Synthes Brief in Support of Motion to Quash, p. 9.

failing a consensus between the parties, this Court may order one. In no event is a wholesale ban on discovery justified.

IV. PATIENT CONFIDENTIALITY CAN BE PRESERVED BY REDACTING FROM THE CLINICAL TRIAL RECORDS ANY INFORMATION WHICH REVEALS THE PATIENT’S IDENTITY.

Synthes insists that, because nonparty medical records are confidential, they are not subject to discovery.¹³ Although the premise of this argument is correct—such records *are* confidential—the conclusion is a non sequitur. The appropriate remedy is not a complete ban on discovery, but rather the redaction of any information which reveals the patient’s identity. *See, e.g., United States v. Zamora*, 408 F. Supp. 2d 295, 299 (S.D. Tex. 2006) (denying motion to quash subpoenas seeking medical records, despite objection of confidentiality: “the appropriate remedy would be to redact any references to [the confidential information]”); *Riley v. Walgreen Co.*, *supra*, 233 F.R.D. at 501 (granting pharmacy customer’s motion to compel production of other incidents of incorrectly-filled prescriptions, but ordering that, because the request sought sensitive information, patient names be redacted to ensure patient confidentiality); *Poliner v. Texas Health Systems*, 201 F.R.D. 437, 438-39 (N.D. Tex. 2001) (granting plaintiff’s motion to compel production of medical peer review records, but ordering that information which revealed patient’s identity be redacted in order to protect patient confidentiality).

Synthes contends that redaction is insufficient, citing *In re Columbia Valley Reg. Med. Ctr.*, 41 S.W.3d 797 (Tex. App.—Corpus Christi 2001, orig. proceeding). But Synthes’ reliance on *Columbia Valley* is misplaced for two reasons. First, “federal law, rather than state law, invariably governs procedural matters in federal courts.” *Camacho v. Texas Workforce Comm’n*, 445 F.3d 407,

¹³ Synthes Brief in Support of Motion to Quash, p. 10.

409 (5th Cir.), *cert. denied*, ___ U.S. ___, 127 S.Ct. 349, 166 L.Ed.2d 44 (2006); *Transcontinental Gas Pipeline Corp. v. Dakota Gasification Co.*, 782 F. Supp. 336, 341 (S.D. Tex. 1991) (“the federal court’s procedural rules . . . are always controlled by federal law”).

Second, even if Texas procedure applied here, redaction rather than a complete prohibition on discovery would still be the appropriate remedy. Most Texas courts—including, significantly, the Texas Supreme Court—hold that patient confidentiality can and should be preserved through the simple expedient of redacting references to the identities of patients and their families. *See, e.g., R.K., M.D. v. Ramirez*, 887 S.W.2d 836, 843 (Tex. 1994); *In re Whiteley*, 79 S.W.3d 729, 733-34 (Tex. App.—Corpus Christi 2002, orig. proceeding); *Alpha Life Ins. Co. v. Gayle*, 796 S.W.2d 834, 836 (Tex. App.—Houston [14th Dist.] 1990, no writ). *Columbia Valley* is an aberration arising under unusual circumstances inapplicable in the present case

A decision considering both of the foregoing points under circumstances almost identical to those in the case at bar is *In re Rezulin Prods. Liab. Litig.*, *supra*. There, as here, the plaintiffs had served subpoenas on physicians who participated in clinical trials, seeking records of patients who were the subjects of those trials. Several of these physicians, who practiced in Texas, objected on the basis of patient confidentiality. Like Synthes, they cited *Columbia Valley*. The court dismissed *Columbia Valley* as “marginally persuasive” for two reasons, one being that “Texas procedural rules do not apply here, and the federal practice in this respect [i.e., redaction of the documents] is quite different.” 178 F. Supp. 2d at 416. The court also concluded that *Columbia Valley* was “unlikely to prove persuasive to the Texas Supreme Court.”

CONCLUSION

For the reasons explained above, Plaintiffs are entitled to the discovery at issue here. Thus,

subject to reasonable restrictions (e.g., a confidentiality agreement to protect Synthes' trade secrets, and the redaction of information identifying patients in the clinical trials), Synthes' motion should be denied.

Respectfully submitted,

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CERTIFICATE OF SERVICE

By my signature above, I certify that a true and correct copy of the foregoing document was delivered to all counsel of record in accordance with the applicable Federal Rules of Civil Procedure on this 5th day of May, 2008.

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO**

CALVIN TIMBERLAKE AND	§	CASE NO. CV 08 80067MISC VRW
KAREN TIMBERLAKE,	§	
Plaintiffs,	§	S.D. Texas Civil Action No.
	§	
VS.	§	6:08-CV-00004
	§	Hearing Stayed by Order
	§	Dated April 25, 2008
SYNTHES SPINE COMPANY, L.P., et. al.,	§	
Defendants.	§	

**ORDER DENYING DEFENDANT SYNTHES SPINE COMPANY, L.P.'S MOTION TO
QUASH OR, IN THE ALTERNATIVE, STAY PLAINTIFFS' THIRD-PARTY
SUBPOENA ON JIM ZUCHERMAN, M.D.**

ON THIS _____ day of _____, 2008, came on to be heard Defendant Synthes Spine Company, L.P.'S Motion To Quash Or, In The Alternative, Stay Plaintiffs' Third-Party Subpoena On Jim Zucherman, M.D. and this Court is of the opinion that said Motion should be DENIED.

IT IS ORDERED, ADJUDGED AND DECREED, that Defendant Synthes Spine Company, L.P.'S Motion To Quash Or, In The Alternative, Stay Plaintiffs' Third-Party Subpoena On Jim Zucherman, M.D. is hereby DENIED.

SIGNED this _____ day of _____, 2008.

JUDGE PRESIDING